

### **DETAILED ACTION**

Receipt of Amendments/Remarks filed on August 24 2010 is acknowledged.  
Claim 11 was/stands cancelled. Claims 1-2 were amended. Claims **1-10** are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on August 24 2010 was considered by the examiner.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.

3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1-4, 7-8 and 11 under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. (US Patent No. 4895724, cited in the Office action mailed on 4/15/05) in view of Vanderhoff et al. (US Patent No. 6214331, cited in the Office action mailed on 9/3/08) is **withdrawn** in light of Applicants' amendments filed on August 24 2010.

The rejection of claims 5-6 under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. in view of Vanderhoff et al. and in further view of Moriguchi et al. (US Patent No. 4879340, cited in the Office action mailed on 4/15/05) is **withdrawn** in light of Applicants' amendments filed on August 24 2010.

The rejection of claim 9 under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. in view of Vanderhoff et al. and in further view of Martin et al. (US Patent

No. 6162537, cited in the Office action mailed on 9/3/08) is **withdrawn** in light of Applicants' amendments filed on August 24 2010.

The rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. in view of Vanderhoff et al. and in further view of Liu et al. (US Patent No. 6096344, cited in the Office action mailed on 9/3/08) is **withdrawn** in light of Applicants' amendments filed on August 24 2010.

**Modified Rejection Based on amendments in the reply filed on August 24 2010**

**Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 9643066 (cited on PTO Form 1449) in view of Adachi et al. (Chem. Pharm. Bull. 1990, cited in the Office action mailed on 2/25/10).**

**Applicant Claims**

Applicants claim a collagen free cosmetic preparation comprising aqueous solutions of chitosans cross-linked to  $\beta$ -(1,3) glucans with diisocyanates and/or dialdehydes.

Applicants claim a method of preparing collagen free cosmetic preparations comprising admixing a solution which an aqueous solution of  $\beta$ -(1,3) adding a cross-linking agent selected from the group consisting of diisocyanates and dialdehydes and removing water from the mixture.

**Determination of the Scope and Content of the Prior Art  
(MPEP §2141.01)**

DE '066 (citations are directed to the machine translation) is directed to a collagen free cosmetic preparation. It is formed by crosslinking cationic biopolymers with polyols and diisocyanates and/or dialdehydes followed by water removal (page 1, 5<sup>th</sup> paragraph). Cationic biopolymers taught include chitosan (page 1, paragraph 8). Crosslinking agents taught include diisocyanates which have the formula  $O=CN[X]-NC=O$  and dialdehydes which have the formula  $OHC-[Y]-CHO$ . Examples include glutaraldehyde (page 2, crosslinking agent section). It is taught that for the mechanical properties of the fleeces, it has been shown to be of advantage to add natural and synthetic fibers (page 2, paragraph 7). As exemplified the water is removed by freeze-drying. It is taught that surfactants that can be added to the formulation. Examples of surfactants include polyols and polyalkylene glycols (page 3, number 6 and 13).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims  
(MPEP §2141.012)**

DE '066 does not teach that the polyol is a beta-(1,3)-glucan. However, this deficiency is cured by Adachi et al.

Adachi et al. is directed to macrophage activation *in vitro* by chemically crosslinked beta-(1,3)-glucans. It is taught that beta-(1,3)-glucans are anti-tumor and posses gel-forming ability. It is taught that crosslinking of these glucans is important for the manifestation of biological activities (page 988, first paragraph).

***Finding of Prima Facie Obviousness Rationale and Motivation  
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of DE '066 and Adachi et al. and utilize beta-glucans as the polyol component of the composition. One of ordinary skill in the art would have been motivated to beta-glucans as they are known polyols which possess anti-tumor activity and whose biological activity is manifested upon cross-linking. Therefore, since DE '066 teach utilizing polyols for crosslinking to chitosan with additional crosslinking agents such as dialdehydes and diisocyanates, one of ordinary skill in the art would have been motivated to utilize beta-glucans in order to provide anti-tumor activity to the compositions as taught by Adachi et al.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

***Response to Arguments***

Applicants argue that (1) DE '066 is discussed on page 1 of the present application and it states that DE '066 have unsatisfactory dermatological compatibility. Applicants argue that (2) Adachi et al. is not in a cosmetic field and that one of ordinary skill in the art would not consider it a polyol.

Applicants' arguments filed August 24 2010 have been fully considered but they are not persuasive.

Regarding applicants' first argument, DE '066 states the compositions are utilized as humidity masks for face and hands, therefore their use as cosmetic preparations would be obvious. Applicants' have not presented any evidence that the compositions can not be utilized for dermatological purposes.

Regarding applicants' second argument, firstly DE '066 gives no limiting definition of the polyols to be utilized. It teaches they preferably possess 2 to 15 carbons but this does not mean they are exclusively only these. Furthermore, the monomers of 1,3-beta-glucan are sugar alcohols just like sorbitol or mannitol. A polyol by definition is an alcohol containing multiple hydroxyl groups (see [thefreedictionary.com](http://thefreedictionary.com), submitted on PTO-892). A beta-glucan is an alcohol with multiple hydroxyl groups. The question to be asked is would one of ordinary skill in the art been motivated to utilize the specific polyol 1,3-beta-glucan, the examiner maintains that it would be based on Adachi et al. teaching that it possess antitumor activity. Applicants have not demonstrated the unexpectedness of this particular polyol over those taught in DE '066. While Adachi et al. does not expressly state that the glucans can be utilized in cosmetics, the reference is generally directed towards the activity of these compounds. It is this activity that would have prompted one of ordinary skill in the art to look at the Adachi et al. reference. Therefore, the rejection is maintained as applicants' have not provided any persuasive arguments or evidence of unexpectedness of 1,3-beta-glucan.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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